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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/709,246	04/23/2004	Mark C. Boomer	101896-0242	3245
21125 7590 11/23/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER HOFFMAN, MARY C	
			ART UNIT 3733	PAPER NUMBER
			NOTIFICATION DATE 11/23/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary

Application No.

10/709,246

Applicant(s)

BOOMER ET AL.

Examiner

Mary Hoffman

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2007.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 7-10, 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 11-19 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/14/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11-18 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mears (U.S. Patent No. 4,620,533) in view of Lin et al. (U.S. Patent No. 6,413,257).

Mears discloses an implantable spinal connector comprising a clamp member (FIG. 12) having top and bottom portions that are connected to one another at a terminal end thereof such that the top and bottom portions are movable between an open position in which the top and bottom portions are spaced a distance apart from one another, and a closed position in which the clamp member is adapted to engage a spinal fixation element there between, the clamp member further including a bore extending through the top and bottom portions for receiving a locking mechanism for locking the top and bottom portions in the closed position, the bore in the bottom portion being internally threaded for mating with corresponding threads formed on at least a portion of the locking mechanism. The implantable spinal connector further comprising a recess formed between the top and bottom portions for seating a spinal fixation

element. The recess is formed adjacent to said terminal end for seating a spinal fixation element therein. The recess is formed in at least one of the inferior surface of the top portion and the superior surface of the bottom portion. The recess is formed in each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member. The recess has a concave shape defines a substantially cylindrical recess when the clamp member is in the closed position. The top and bottom portions are biased to an open position such that a force greater than the biasing force must be applied to move the top and bottom portions to the closed position. The implantable spinal connector further comprises a locking mechanism (ref. #24) disposable through the bore and effective to lock the top and bottom portions in the closed position to retain a spinal fixation element there between. The locking mechanism comprises a fastening element having a head (at ref. #25) and a shaft, and wherein the bore formed in the top portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element. The bore in the top portion of the clamp member is internally threaded for mating with corresponding threads formed on at least a portion of the shaft (Applicant is reminded that "top" and "bottom" are relative terms, and the device can be flipped upside, making the top the bottom and the bottom the top). The fastening element includes a flange formed there around (flange-like head portion at ref. #25) and adapted to at least temporarily mate the fastening element to a spinal anchoring device. The fastening element includes a mating element formed on a distal-most end thereof for

mating with a driver tool. The clamp member is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position. An implantable spinal connector for mating a spinal fixation element to a spinal anchoring device comprising a clamp member having top and bottom portions that are connected to one another at a terminal end thereof such that the top and bottom portions are movable between an open position and a closed position; a recess formed between a superior surface of the top portion of the clamp member and an inferior surface of the bottom portion of the clamp member, the recess being adapted to seat a spinal fixation element therein; axially aligned, concentric bores extending through the top and bottom portions at a location spaced apart from the recess, the bores being configured to receive a locking mechanism for locking the top and bottom portions in the closed position; and a substantially planar inferior surface extending along the bottom portion of the clamp member (see bottom planar surface, or, flipping the device, the planar surface in which ref. #22 sits can be considered the substantially planar inferior surface extending along the bottom portion of the clamp member) and configured to engage a spinal fixation plate. At least one of the concentric bores includes threads formed therein.

Mears discloses the claimed invention except for the superior and inferior surfaces of the top and bottom portions tapering away from each other toward the terminal end; and for the top and bottom portions are biased to a closed position (Mears

disclose top and bottom portions biased to an open position), and the threads formed on at least a portion of the shaft being left-handed threads.

Lin et al. discloses a clamp with superior and inferior surfaces of the top and bottom portions tapering away from each other toward the terminal end (see FIG. 8) in order to increase the clamping force (col. 4, lines 20-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Mears with superior and inferior surfaces of the top and bottom portions tapering away from each other toward the terminal end in view of Lin et al. in order to increase the clamping force.

Furthermore, regarding claims 17 and 25, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the threads formed on at least a portion of the shaft of Mears in view of Lin et al. being left-handed threads, since it is a configuration a person ordinary skill in the art would find obvious for the purpose of providing threads. In re Dailey and Eilers, 149 USPQ 47 (1966). Regarding claim 11, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the top and bottom portions of Mears in view of Lin et al. being biased to a closed position, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claims 1-6, 11-19 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walulik (U.S. Patent No. 6,277,119) in view of Lin et al. (U.S. Patent No. 6,413,257).

Walulik discloses an implantable spinal connector comprising a clamp member (FIG. 5c) having top and bottom portions that are connected to one another at a terminal end thereof such that the top and bottom portions are movable between an open position in which the top and bottom portions are spaced a distance apart from one another, and a closed position in which the clamp member is adapted to engage a spinal fixation element there between, the clamp member further including a bore extending through the top and bottom portions for receiving a locking mechanism for locking the top and bottom portions in the closed position, the bore in at least one of the top and bottom portions being internally threaded for mating with corresponding threads formed on at least a portion of the locking mechanism. The implantable spinal connector further comprising a recess formed between the top and bottom portions for seating a spinal fixation element. The recess is formed adjacent to said terminal end for seating a spinal fixation element therein. The recess is formed in at least one of the inferior surface of the top portion and the superior surface of the bottom portion. The recess is formed in each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member. The recess has a concave shape defines a substantially cylindrical recess when the clamp member is in the closed position. The top and bottom portions are biased to an open position such that a force greater than the biasing force must be applied to move the top and bottom portions to the closed

position. The implantable spinal connector further comprises a locking mechanism disposable through the bore and effective to lock the top and bottom portions in the closed position to retain a spinal fixation element there between. The locking mechanism comprises a fastening element having a head and a shaft, and wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element. The fastening element includes a flange formed there around and adapted to at least temporarily mate the fastening element to a spinal anchoring device. The bore in the top portion of the clamp member is internally threaded for mating with corresponding threads formed on at least a portion of the shaft. The fastening element includes a mating element formed on a distal-most end thereof for mating with a driver tool. The mating element comprises a socket. The clamp member is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position. An implantable spinal connector for mating a spinal fixation element to a spinal anchoring device comprising a clamp member having top and bottom portions that are connected to one another at a terminal end thereof such that the top and bottom portions are movable between an open position and a closed position; a recess formed between a superior surface of the top portion of the clamp member and an inferior surface of the bottom portion of the clamp member, the

recess being adapted to seat a spinal fixation element therein; axially aligned, concentric bores extending through the top and bottom portions at a location spaced apart from the recess, the bores being configured to receive a locking mechanism for locking the top and bottom portions in the closed position; and a substantially planer inferior surface extending along the bottom portion of the clamp member and configured to engage a spinal fixation plate. At least one of the concentric bores includes threads formed therein.

Walulik discloses the claimed invention except for the superior and inferior surfaces of the top and bottom portions tapering away from each other toward the terminal end; and the top and bottom portions are biased to a closed position (Walulik disclose top and bottom portions biased to an open position), and the threads formed on at least a portion of the shaft being left-handed threads.

Lin et al. discloses a clamp with superior and inferior surfaces of the top and bottom portions tapering away from each other toward the terminal end (see FIG. 8) in order to increase the clamping force (col. 4, lines 20-25).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Walulik with superior and inferior surfaces of the top and bottom portions tapering away from each other toward the terminal end in view of Lin et al. in order to increase the clamping force.

Furthermore, regarding claims 17 and 25, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the threads formed on at least a portion of the shaft of Walulik in view of Lin et al. being

left-handed threads, since it is a configuration a person ordinary skill in the art would find obvious for the purpose of providing threads. In re Dailey and Eilers, 149 USPQ 47 (1966). Regarding claim 11, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the top and bottom portions of Walulik in view of Lin et al. being biased to a closed position, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Application/Control Number:
10/709,246
Art Unit: 3733

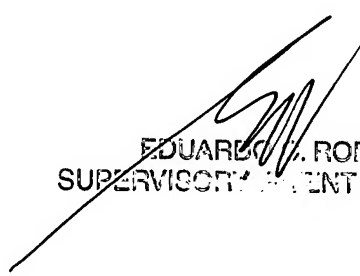
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



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